UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 10, 2022

Invivyd, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-40703**	**85-1403134**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1601 Trapelo Road, Suite 178 **Waltham, MA**	**02451**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 819-0080

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	**IVVD**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 10, 2022, Invivyd, Inc. (the "Company") issued a press release providing a corporate update and announcing its financial results for the quarter ended September 30, 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information furnished pursuant to this Item 2.02, including the attached Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any of the Company's filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INVIVYD, INC.

Date: November 10, 2022

By: /s/ Jill Andersen
Jill Andersen
Chief Legal Officer and Corporate Secretary

Exhibit 99.1

Invivyd Reports Third Quarter 2022 Financial Results and Business Highlights

Novel monoclonal antibody combination candidate (NVD200) on track to advance into clinical trials in Q1 2023

$419 million in cash, cash equivalents and marketable securities expected to support operating runway into Q2 2024

Conference call scheduled for Thursday, November 10th at 4:30 p.m. ET

Waltham, MA – November 10, 2022 – Invivyd, Inc. (Nasdaq: IVVD) a clinical-stage biopharmaceutical company on a mission to protect humanity from serious viral respiratory diseases, today announced financial results and business highlights for the third quarter ended September 30, 2022.

"It has been a productive quarter starting with a corporate rebrand emphasizing our commitment to efficiently generating antibodies that transcend the limits of naturally occurring immunity to prevent and treat life-threatening viral infections, including COVID-19," said David Hering, chief executive officer of Invivyd. "Innovation in the monoclonal antibody space is desperately needed to create new options that overcome diminishing efficacy due to the rapidly changing nature of the virus. Leveraging our integrated discovery platform, we have engineered NVD200, our recently announced combination antibody product candidate which has potential to provide broad and durable protection against currently circulating and future COVID-19 variants. We look forward to advancing this important program into the clinic in the first quarter of 2023."

Third Quarter and Recent Business Highlights

- In July, the Company named David Hering chief executive officer. Dave had served as the company's interim chief executive officer and chief operating officer since February 2022. Dave brings a broad biotech and infectious disease background having served in numerous leadership roles at Novartis and Pfizer, including most recently as the president of North America Vaccines of Pfizer, Inc. where he led the launch of the first and market leading COVID-19 vaccine and subsequently the head of the mRNA franchise.
- Completed corporate rebranding and name change to reflect the Company's focus on leveraging its best-in-class integrated discovery platform to develop and commercialize antibodies that transcend the limits of the human immune system to better prevent and treat viral respiratory diseases.
- In September, the Company announced that it will advance NVD200 into clinical trials in the first quarter of 2023. NVD200 is a combination of two monoclonal antibodies, one being a re-engineered version of adintrevimab, which demonstrated clinically meaningful results in Phase 2/3 trials prior to the emergence of the Omicron variant. NVD200 has demonstrated potent *in vitro* neutralizing activity against prior and current SARS-CoV-2 variants of concern, including Omicron sublineages, as well as the more antigenically divergent SARS-CoV-1.
- The Company entered into a facilities lease agreement for a total of 9,600 square feet of dedicated laboratory and office space in Newton, Massachusetts. The increased space will enable the build out of additional discovery and development capabilities to maximize the potential of Invivyd's integrated discovery platform.

- In September, the Company entered into a Platform Transfer Agreement with Adimab for the right to use its platform technology to discover, engineer and optimize antibodies.
- Invivyd presented four posters in October at ID Week 2022 in Washington, D.C. that shared data from several studies surrounding adintrevimab, including data from the Phase 1 and Phase 2/3 clinical trials.
- In October, the Company announced key leadership appointments with Fred Driscoll joining as interim chief financial officer and Christine Lindenboom joining the board of directors. The changes broaden the Company's industry expertise in support of its development plans. The company also announced headcount changes to align resources to focus on its key programs, improve capital efficiency and operate on an accelerated timeline.

Third Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $419 million as of September 30, 2022.
- **Cash Runway:** Based on current operating plans, Invivyd expects its existing total cash, cash equivalents and marketable securities will enable the company to fund its operating expenses into the second quarter of 2024.
- **Research & Development (R&D) Expenses (including In-process Research and Development):** R&D expenses were $34.1 million for the third quarter of 2022, compared to $49.4 million for the comparable period of 2021. This decrease is attributable to wind-down of adintrevimab clinical trials and manufacturing, partially offset by contract manufacturing expenses related to the production of materials for use in NVD200 clinical trials and non-clinical studies.
- **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were $13.2 million for the third quarter of 2022, compared to $11.1 million for the comparable period of 2021. This increase is attributable to higher public company costs and personnel related expenses.
- **Net Loss and Net Loss per Share:** Net loss was $45.1 million for the third quarter of 2022, compared to $60.4 million for the comparable period in 2021. Basic and diluted net loss per share was $0.42 for the third quarter of 2022, compared to $0.98 for the comparable period in 2021.

Conference Call

In connection with this announcement, Invivyd will host a conference call and webcast today at 4:30 p.m. ET. A live audio webcast will be available at invivyd.com/investors. Interested parties may also register for the webcast via this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available via the company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

About Invivyd

(Nasdaq: IVVD)

Invivyd, formerly Adagio Therapeutics (Nasdaq: ADGI), is a biopharmaceutical company on a mission to protect humanity from serious viral respiratory diseases. The company is developing antibodies to transcend the limits of naturally occurring immunity and provide superior protection from viral diseases, beginning with COVID-19. Invivyd's technology works at the intersection of evolutionary virology, predictive modeling, and antibody engineering, and is designed to identify high-quality, long-lasting antibodies with a high barrier to viral escape. The company's integrated discovery platform is generating a robust pipeline of products for use in both prevention and treatment of disease. NVD200, Invivyd's

first antibody combination product candidate for the prevention and treatment of COVID-19, includes a re-engineered version of adintrevimab, an investigational monoclonal antibody which demonstrated clinically meaningful results against multiple variants of concern in global Phase 2/3 clinical trials for the prevention and treatment of COVID-19, prior to the emergence of Omicron. The safety and efficacy of adintrevimab have not been established. The company also has multiple discovery stage candidates for the prevention of seasonal influenza. Visit www.invivyd.com to learn more.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "could," "expects," "intends," "potential," "projects," and "future" or similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements include statements concerning, among other things, the future of the COVID-19 landscape including the expectation of continued evolution and emergence of new variants and subvariants; our ongoing research and clinical development plans and the timing thereof; our plans to advance adintrevimab, NVD200, or other early stage candidates as a potential prophylaxis and treatment option for COVID-19, including disease caused by most variants, as either a single or combination agent, including our intention to initiate clinical development of NVD200 in the first quarter of 2023; the potential for adintrevimab and NVD200 to demonstrate activity against predominant SARS-CoV-2 variant(s), provide durable and broad protection against currently circulating and future COVID-19 variants, and to overcome diminishing efficacy due to the rapidly changing nature of the virus in the U.S. and globally; our expected cash runway, our plans, technology and resources to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and seasonal influenza, in the U.S. and globally; the benefit of the increased leased laboratory space to allow for additional discovery and development capabilities and output from our integrated discovery platform; the implementation and impact of the restructuring plan and the intended benefits to the company from the plan; and other statements that are not historical fact. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements, including, without limitation: we may not realize the expected benefits from the restructuring plan, including accelerated timelines and enhanced discovery and development process and outcomes, and we may incur costs associated with implementation of the restructuring plan in addition to those currently contemplated; potential disruptions to the business as a result of the restructuring plan and the management transition; we may not realize discovery or development benefits from the additional leased lab space; the impacts of the COVID-19 pandemic on our business and those of our collaborators, our clinical trials and our financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of adintrevimab, NVD200, or other pipeline candidates or combination of candidates based on neutralizing activity in pre-clinical studies; variability of results in models used to predict activity against SARS-CoV-2 variants of concern; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process, including the outcome of our discussions with regulatory authorities concerning our clinical trials; whether adintrevimab, NVD200, or any other pipeline candidate or combination of candidates is able to demonstrate activity against predominant SARS-CoV-2 variant(s), provide durable and broad protection against currently circulating and future COVID-19 variants, or overcome diminishing efficacy due to the rapidly changing nature of the virus in the U.S. and globally; whether we are able to successfully submit an emergency use authorization in the

future, and the outcome of any such emergency use authorization submission; whether research and development efforts will improve efficacy of adintrevimab against predominant variants or identify additional monoclonal antibodies or combination of antibodies for the prevention and treatment of COVID-19 and other infectious diseases; whether research and development efforts will identify and result in safe and effective therapeutic or preventative options for other infectious diseases in the U.S. or globally and whether we have adequate funding to meet future operating expenses and capital expenditure requirements. Other factors that may cause our actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, each filed with the Securities and Exchange Commission (the “SEC”), our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 to be filed after the issuance of this release, and in our other filings with the SEC, and in Invivyd’s future reports to be filed with the SEC and available at www.sec.gov. Such risks may be amplified by the impacts of the COVID-19 pandemic. Forward-looking statements contained in this press release are made as of this date, and Invivyd undertakes no duty to update such information whether as a result of new information, future events or otherwise, except as required under applicable law.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

Contacts

Media Contact:

Tony Berry, Evoke Canale
774-317-0422
anthony.berry@evokegroup.com

Investor Contact:

Chris Brinzey, ICR Westwicke
339-970-2843
chris.brinzey@westwicke.com

INVIVYD, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 278,152	$ 542,224
Marketable securities	140,517	49,194
Prepaid expenses and other current assets	2,927	25,293
Total current assets	421,596	616,711
Property and equipment, net	1,429	83
Operating lease right-of-use assets	1,486	—
Other non-current assets	236	3,297
Total assets	$ 424,747	$ 620,091
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 16,770	$ 5,783
Accrued expenses	28,974	56,277
Operating lease liability, current	329	—
Other current liabilities	53	—
Total current liabilities	46,126	62,060
Early-exercise liability	1	6
Operating lease liability, non-current	1,177	—
Other non-current liability	—	6
Total liabilities	47,304	62,072
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 108,957,401 shares issued and outstanding at September 30, 2022; 1,000,000,000 shares authorized, 111,251,660 shares issued and 110,782,909 shares outstanding at December 31, 2021	11	11
Treasury stock, at cost; 0 shares and 468,751 shares at September 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	866,238	850,125
Accumulated other comprehensive income (loss)	46	(8)
Accumulated deficit	(488,852)	(292,109)
Total stockholders' equity (deficit)	377,443	558,019
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 424,747	$ 620,091

INVIVYD, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Operating expenses:				
Research and development[1]	$ 30,131	$ 45,366	$ 159,295	$ 114,465
Acquired in-process research and development[2]	4,000	4,000	4,000	7,500
Selling, general and administrative	13,200	11,052	36,524	21,853
Total operating expenses	47,331	60,418	199,819	143,818
Loss from operations	(47,331)	(60,418)	(199,819)	(143,818)
Other income (expense):				
Other income (expense), net	2,244	43	3,076	70
Total other income (expense), net	2,244	43	3,076	70
Net loss	(45,087)	(60,375)	(196,743)	(143,748)
Other comprehensive income (loss)				
Unrealized gain on available-for-sale securities, net of tax	46	3	54	3
Comprehensive loss	$ (45,041)	$ (60,372)	$ (196,689)	$ (143,745)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.42)	$ (0.98)	$ (1.82)	$ (7.06)
Weighted-average common shares outstanding, basic and diluted	108,420,674	61,297,086	108,154,397	20,346,771

(1) Includes related-party amounts of $1,742 and $6,027 for the three and nine months ended September 30, 2022, respectively, and $1,826 and $2,261 for the three and nine months ended September 30, 2021, respectively.

(2) Includes related-party amounts of $4,000 for both the three and nine months ended September 30, 2022, and $4,000 and $7,500 for the three and nine months ended September 30, 2021, respectively.